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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,626	08/30/2001	Norman G. Anderson	42159	6779

7590 10/20/2004

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EXAMINER	
MARSCHEL, ARDIN H	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/941,626	ANDERSON ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See explanation as attached.*.

3. ☒ Applicant's reply has overcome the following rejection(s): The 102 rejection of claim 63 based on Reyes et al.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *of reasons of record as further explained as attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: *59*.

   Claim(s) rejected: *1-14,16,59 and 63-68*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

Continuation of 10. Other: Corrected (for typo) copy of an 892 form, mailed previously on 11/5/03 (2 sheets).

DETAILED ACTION

Further Explanation of item # 2 on the enclosed Advisory action:

The proposed amendments to claim 1 add new issues that would require further consideration and/or search, such as the phrase "wherein one of the nucleic acids is from a different type of infectious particle than another one of the nucleic acids" which adds the new issues of identification of "different" types both being "different" and what typing is meant regarding a different "type" of infectious particle. This phrase also adds the new issue of "one" nucleic acid being from a different type of infectious particle that "another one". Additionally, proposed claim 1, line 10, cites the new issue of deducing a nucleotide sequence via the phrase "deduce a nucleotide sequence". Also, plurality of "different types" of infectious particles per se are identified as cited in claim 1, line 12. These are new issues that were not present in the claims prior to this proposed amendment and require further consideration and/or search.

Another new issue is the raising of a rejection under 35 U.S.C. § 112, second paragraph, if the proposed amendment had been entered because in line 10 of proposed claim 1 the deduction of a nucleotide sequence is cited as being directed to a "sequenced portion" of nucleic acids. If the sequenced portion had been "sequenced" what deduction is needed or appropriate if it already was sequenced?

NEW MATTER is also proposed regarding the amendment to claim 64 directed to the sample not being cultured. It is noted that 7, as filed, cites the not cultured practice but directed therein to "the infectious particle" and not to "the sample" as now proposed for claim 64. The "different families" limitation proposed for claim 65 also is NEW MATTER as this has neither been found as filed nor pointed to regarding support by applicants.

The above new issues also do not place the application in better form for appeal nor materially reduce or simplify the issues for appeal.

Further explanation of item # 5 on the enclosed Advisory action:

The rejection based on NEW MATTER of claims 63 and 65-68 is maintained and reiterated from the previous office action, mailed 5/4/04.

Regarding claim 63, applicants argue that pooled samples from multiple humans is disclosed on page 14, last paragraph, page 15, first half, and page 24, first two paragraphs. Each of these citations are herein discussed as being non-persuasive as follows. On page 14, what is meant by the last paragraph is confusing in that on page 14, the last full paragraph extends from lines 8-24, and which is followed by a partial paragraph in lines 25-32 which bridges pages 14 and 15. Both will be commented on. On page 14, lines 8-24, "human pathogenic viruses" are cited in lines 10-11, but nothing regarding the characterization of samples from which they are obtained such as pooled samples as instantly claimed. Further on page 14, lines 20-21, cite "mixtures antibodies from convalescent individuals or individuals" which are mixed antibody samples and not infectious particle samples which are pooled as instantly claimed.

On page 14, lines 25-32, in lines 26-27, mixed infectious particle samples are cited but without any indication as to whether such mixed samples are from humans. This is additionally emphasized as being animal and non-human samples via the agricultural and veterinary words in lines 30 and 31, respectively, as well as the reference to a slaughterhouse in line 31.

On page 15, first half, lines 1-5, the samples apparently are from environmental sources such as trees, rocks, and plants without any human source cited, much less any pooling.

On page 15, first half, first full paragraph, pooled samples are cited but only from a country, region, or extraterrestrial sources, again not citing any human individual samples. Swine and/or duck workers are described in line 11, but without any pooling therewith nor even what, if any sampling is obtained in order to "periodically" check them. Thus, antibody checks may or may not be the checking therein meant vs. possibly infectious particle checking albeit neither being described in a written disclosure therein. Various other sources are monitored or checked as described in lines 12-17, but also without any pooling or even any sampling practice described.

On page 24, first two paragraphs, population study is described but without pooling of samples being performed in order to carry out such a study. On page 24, lines 10-11, pooled samples are described however without indicating whether these are pooled from individual humans or not. Also the samples being pooled are "Concentrated viral suspension" which are not cited as being a sample type in any of the instant claims.

In summary the NEW MATTER rejection regarding NEW MATTER in instant claim 63 is maintained.

Claim 65 still is deemed to contain NEW MATTER as described in the previous office action, mailed 5/4/04. Applicants argue that page 12, first full paragraph, cites support for claim 65. Consideration of said paragraph on page 12 reveals that screening of microorganisms simultaneously is cited but without any database characterization at all which is the subject matter of claim 65. Thus, said page 12 citation does not contain disclosure that overcomes this NEW MATTER issue. Applicants further cite page 36, lines 2-10, to support instant claim 65. Consideration of said page 36 citation reveals that a large database of viruses from all virus families available, but does not indicate that these are particularly "unrelated" viruses or even

families of viruses for that matter. Also, said page 36 citation is directed to viruses and not the broadly cited "infectious particle" subject matter of claim 65. Thus, the NEW MATTER rejection regarding NEW MATTER in claim 65 is maintained.

Claim 66 still is deemed to contain NEW MATTER as described in the previous office action, mailed 5/4/04. Applicants argue that page 7, last 5 lines, cites supporting description for claim 66. Consideration of said page 7 citation reveals firstly that the method is therein cited as a quality control method which is not a method type as instantly claimed. Secondly, the "absence of viruses" is described which lacks any specificity as in instant claim 66 which contains the phrase "specific infectious particle". Applicants also point to page 15, first full paragraph. Consideration of said page 15, first full paragraph, reveals that checking for new viruses is therein described but without any suspicion or "suspected of containing" concept therein as in claim 66, nor any specificity as in the claim 66 phrase "specific infectious particle. Applicants further cite page 25, last paragraph, regarding claim 66. Consideration of page 25, last paragraph, reveals that generic quality control checking is cited such as searching for unculturable microorganisms as well as screening for the presence of known or unknown infectious particles. This lacks any "suspected of containing" concept as in claim 66 as well as any indication of a "specific infectious particle" as now set forth in claim 66. Applicants additionally cite page 29, third and fourth paragraphs. Consideration of said paragraphs reveals that "virus-free" animal products are cited which are generic and lacks any "specific infectious particle" citation. On page 29, line 19, the phrase "free of unknown viruses" (plural) is cited but without any suspected concept nor any specificity regarding a "specific infectious particle" (singular) as in claim 66. Therefore, the NEW MATTER described in claim 66 is still reasonably deemed NEW MATTER as maintained from the previous office action, mailed 5/4/04.

The NEW MATTER rejection of instant claim 67 is maintained from the previous office action, mailed 5/4/04, and has not been argued by applicants.

Claim 68 still is deemed to contain NEW MATTER as described in the previous office action, mailed 5/4/04. Applicants argue that page 11, lines 19-23, supports claim 68. Consideration of said citation on page 11 reveals that an array of oligonucleotide probes is cited but without any immobilization described nor that the array is of the microarray type. It is noted that oligonucleotide arrays are not necessarily immobilized, nor utilizing a microarray, since Cot curves are well known which utilize soluble arrays of nucleic acids of various types for hybridization study, just for one example of many of soluble techniques. A microarray also is a particular type of array which is not disclosed on page 11 as being an array of the micro-array type. Applicant further point to page 17, lines 3-4. Consideration of said page 17 citation reveals a lack of any microarray or immobilization practice thus failing to give written support for the NEW MATTER in claim 68. Applicants allege that "other locations" support claim 68, but this is an allegation without factual support as to what other locations are meant and therefore non-persuasive.

The rejections of all pending claims based on vagueness and indefiniteness is maintained and reiterated from the previous office action, mailed 5/4/04. Applicants argue that the amending of claim 1 avoids this rejection. As said amending has not been entered, this rejection is maintained. Applicants also alleged "misinterpretations" but did not indicate what was misinterpreted which make this an allegation without factual support and thus non-persuasive. Applicants further argue that the most important feature of the claim is the determination of infectious particle identity by directly or indirectly sequencing. It is noted that there are no "directly" or "indirectly" sequencing limitations either in the presently pending claims or in proposed claim

wording. Applicants may intend complement sequencing to be indirect sequencing however, such complement sequencing is not cited in the claims as being an indirect sequencing practice. Databases for identification of infectious particles may contain either a nucleic acid sequence and/or its complement. Thus, a complement in such a database would not itself be an indirect data entry.

No argument has been seen in arguments of applicants regarding the vagueness and indefiniteness rejection based on "complementary" and this basis for rejection is therefore maintained.

A rejection under 35 U.S.C. § 112, second paragraph, would still be applicable, even if the proposed amendment had been entered because in line 10 of proposed claim 1 the deduction of a nucleotide sequence is cited as being directed to a "sequenced portion" of nucleic acids. If the sequenced portion had been "sequenced", what deduction is needed or appropriate if it already was sequenced?

The rejection of claims 1, 3, 4, 6, 7, 9, 10, 12, 13, 59, and 64 based on 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Reyes et al. (P/N 5,218,099) is maintained and reiterated from the previous office action, mailed 5/4/04. It has been noted that claim 63 is no longer included in the list of instant claim rejected over Reyes et al. because it was inadvertently previously included as rejected but is noted as being dependent from instant claim 2 which is not disclosed in Reyes et al.

Applicants argue that claim amending overcomes this rejection. The claim amending has not been entered as discussed above and thus the claims remain rejected as set forth in the previous office action, mailed 5/4/04. Applicants lengthy arguments regarding Reyes et al. is directed solely to the particular proposed claim amending regarding detection of different infectious particle types in a sample whether old, new, or known. Since the proposed claim amending has not been entered these

arguments are non-persuasive because the claims as pending do not require "different" infectious particle detection in a sample. In response to certain arguments, applicants on page 9 of REMARKS, filed 8/4/04, argue that Figures 1-5 are partial sequences because of being too short to encode a virus, because of lacking a N-terminal methionine as well as regulatory sequences and being prepared via random priming. In response, these are allegations without any factual support as to these sequences being from the same singular virus, especially since humans as well as chimpanzees are separate sources for these sequences, thus being clearly different virus types at least being from different sources thus being of the human or chimpanzee type whether different in nucleic acid content and/or sequence or not. For this reason, even if amendment, proposed 8/4/04, is entered this rejection would be maintained. Of particular interest is the argument on page 11 of REMARKS, filed 8/4/04, regarding instant claims 5 and 6 wherein applicants argue that Reyes et al. does not mention ever finding a known virus. This is contrary to the factual basis in Reyes et al. set forth in the previous office action, mailed 5/4/04, wherein Reyes et al. was set forth as performing comparisons between samples and those from a publication which clearly is known at the time of the comparison. Applicants argue that claim 10 and 64 are not anticipated via arguing that sedimentation values are never utilized in Reyes et al. for separation. In response, Reyes et al. was cited previously as describing sedimentation values for purification and thus separation of the virus from other materials in a sample and thus this argument is contrary to the factual basis for this rejection and therefore non-persuasive.

Applicants then argue the prior art rejection regarding instant claim 14 and 16 which is confusing because instant claims 14 and 16 are not rejected based on Reyes et al.

Applicants then argue regarding claims 63 and 65-68. Claim 63 has been removed as rejected hereinunder. Also claims 65-68 have not been rejected based on Reyes et al. in the previous office action, mailed 5/4/04.

The objections due to informalities in the specification and claim 59 is also maintained due to non-entry of the amendments. All amendments, filed 8/4/04, have been denied entry as partial entry is confusing and generally leads to processing errors.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H. Marschel 10/5/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER

October 5, 2004